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Application No. 10/540,743 Information Disclosure Statement Paper dated November 15, 2006 Attorney Docket No. 3998-051955

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

10/540,743

Confirmation No.

2402

**Applicants** 

Duncan J. STEWART et al.

Filed

June 24, 2005

Title

**ENCAPSULATED CELL THERAPY** 

Art Unit

Not Yet Assigned

Examiner Name

Not Yet Assigned

Customer No.

28289

MAIL STOP AMENDMENT Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the requirements of 37 CFR §§ 1.56, 1.97, and 1.98, the Applicants hereby submit this Information Disclosure Statement together with completed Forms PTO/SB/08A-B and one copy of the foreign references and articles listed thereon. The cited U.S. patents are not enclosed pursuant to the waiver of the requirement under 37 C.F.R. § 1.98(a)(2)(i) for U.S. national patent applications filed after June 30, 2003.

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 15, 2006.
Bruce L. White (Name of Person Mailing Paper or Fee)
PMAR L. White 11/15/06
Signature Date

{W0270394.1}

Application No. 10/540,743

Information Disclosure Statement Paper dated November 15, 2006

Attorney Docket No. 3998-051955

The references identified on Forms PTO/SB/08A-B were identified by the

Applicants of the instant application.

Pursuant to 37 C.F.R. § 1.97(b)3, no fee is believed to be due for the submission

of this Information Disclosure Statement, as it is being submitted before the mailing date of a

first Office Action on the merits. Nevertheless, the Commissioner for Patents is hereby

authorized to charge any fees which may be required to Deposit Account No. 23-0650. One (1)

original and two (2) copies of this Information Disclosure Statement are enclosed.

Respectfully submitted,

THE WEBB LAW FIRM

 $\mathbf{R}\mathbf{v}$ 

William H. Logsdon

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PTO/SB/08a (07-05)

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Complete if Known 10/540,743 Application Number INFORMATION DISCLOSURE Filing Date June 24, 2005 STATEMENT BY APPLICANT First Named Inventor Duncan J. STEWART Art Unit Not Yet Assigned (Use as many sheets as necessary) **Examiner Name** Not Yet Assigned Sheet of 9 Attorney Docket Number 3998-051955

			U.S. PATENT I	OCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number - Kind Code <sup>2 (if known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US- 4,409,331	10-11-1983	Lim	
	2.	US- 4,352,883	10-05-1982	Lim	
	3.	US- 5,182,111	01-26-1993	Aebischer et al.	
	4.	US- 5,283,187	02-01-1994	Aebischer et al	
	5.	US- 5,389,535	02-14-1995	Aebischer et al	
	6.	US- 4,673,566	06-16-1987	Goosen et al.	
	7.	US- 4,689,293	08-25-1987	Goosen et al.	
	8.	US- 4,806,355	02-21-1989	Goosen et al.	
	9.	US- 4,789,550	12-06-1988	Goosen et al.	
	10.	US- 4,803,168	02-07-1989	Jarvis, Jr.	
	11.	US- 4,391,909	07-05-1993	Lim	
	12.	US- 4,298,002	11-03-1981	Ronel et al.	·
	13.	US- 4,353,888	10-12-1982	Sefton	
	14.	US- 5,262,055	11-16-1993	Bae et al.	
	15.	US- 5,569,462	10-29-1996	Brauker et al.	
	16.	US- 5,344,454	09-06-1994	Clarke et al.	

FOREIGN PATENT DOCUMENTS							
 Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages			
110.	Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	or Relevant Figures Appear	T <sup>6</sup>		
17.	WO 98/05304	02-12-1998	Li, Rebecca				
18.	WO 95/19430	07-20-1995	Kanti, Jain				
19.	PCT/AU90/00281	01-17-1991	Baxter Int.				
20.	PCT/US94-07190	03-13-2000	Gore & Ass.				

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	INFORMATION DISCLOSURE			Filing Date	June 24, 2005
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	21.	US- 5,002,661	03-26-1991	Chick et al.	
	22.	US- 4,829,000	05-09-1989	Kleinman et al.	
	23.	US- 6,004,295	12-21-1999	Langer et al.	
	24.	US- 6,482,406	11-19-2002	Stewart	
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		NON PATENT LITERATURE DOCUMENTS	
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	25.	RAMDI et al., "Influence of matricial molecules on growth and differentiation of entrapped chrondocytes," Experimental Cell Research, (1993), p. 449-454, Vol. 207	
	26.	KANTI et al., "Retrievable, replaceable, macroencapsulated pancreatic islet xenografts," Transplantation (Baltimore), (1995), p. 319-324, Vol. 59, No. 3, (abstract)	
	27.	MARLER et al., "Soft-tissue augmentation with injectable alginate and syngeneic fibroblast," Plastic and Reconstructive Surgery, (2000), p. 2049-2058, Vol. 105, No. 5, (abstract)	
	28.	HALBERSTADT et al., "A hydrogel material for plastic and reconstructive applications injected into the subcutaneous space of a sheep," Tissue Engineering, (April 2002), p. 309-319, Vol. 8, No. 2, (abstract)	
	29.	PARK, "Improved long-term culture of hepatocytes in a hydrogel containing Arg-Gly-Asp (RGD)," Biotechnology Letters, (July 2002), p. 1131-1135, Vol. 24, No. 14, (abstract)	
	30.	BURDICK et al., "Photoencapsulation of osteoblasts in injectable RGD-modified PEG hydrogels for bone tissue engineering," Biomaterials, (2002), p. 4315-4323, Vol. 23	
	31.	NUTTELMAN et al., "Attachment of fibronectin to poly(vinyl alcohol) hydrogels promotes N1H3T3 cell adhesion, proliferation, and migration," Journal of Biomedical Materials Research, (November 2001), p. 217-223, Vol. 57, No. 2	
	32.	MANN et al., "Smooth muscle cell growth in photopolymerized hydrogels with cell adhesive and proteolytically degradable domains: Synthetic ECM analogs for tissue engineering," Biomaterials, (2001), p. 3045-3051, Vol. 22	
	33.	KOH et al., "Molding of hydrogel microstructures to create multiphenotype cell microarrays," Analytical Chemistry, (November 2003), p. 5783-5789, Vol. 75, No. 2, (abstract)	
	34.	KAROUBI et al., "Cell micro-encapsulation with integrin binding proteins prevents anoikis: Implications for adherent cell therapy," Circulation, (October 2003), p. Iv-286, Vol. 108, No. 17 Supplement, (abstract)	

Examiner	Date	
Signature	Consid	lered

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	35.	BORDIGNON et al. "Cell Therapy: Achievements and Perspectives," Haematologica, (1999), p. 1110-1149, Vol. 84	
	36.	LINDVALL et al., "Cell Therapy and Transplantation in Parkinson's Disease," Clinical Chemistry and Laboratory Medicine, (2001), p. 356-361, Vol. 39	
	37.	MIYAMOTO, "Current Progress and Perspectives in Cell Therapy for Diabetes Mellitus," Human Cell, (2001), p. 293-300, Vol. 14, No. 4	
	38.	MORRIS, "Immunoprotection of Therapeutic Cell Transplants by Encapsulation," Trends in Biotechnology, (1996), p. 163-167, Vol. 14	
	39.	ROWLEY et al., "Alginate Hydrogels as Synthetic Extracellular Matrix Materials," Biomaterials, (1999), p. 45-53, Vol. 20	
	40.	RUOSLAHTI, "RGD and other Recognition Sequences for Integrins," Annual Review in Cell and Developmental Biology, (1996), p. 697-715, Vol. 12	
	41.	ULUDAG et al., "Technology of Mammalian Cell Encapsulation," Advanced Drug Delivery Reviews, (2000), p. 29-64, Vol. 42	
	42.	BIANCO et al., "Bone Marrow Stromal Stem Cells: Nature, Biology and Potential Applications," Stem Cells, (2001), p. 180-192, Vol. 19	
	43.	BROWN, et al., "Gene Delivery with Synthetic (non viral) Carriers," International Journal of Pharmaceutics, (2001), p. 1-21, Vol. 229	
	44.	BALLY et al., "Biological Barriers to Cellular Delivery of Lipid-Based DNA Carriers,:" Advanced Drug Delivery Reviews, (1999), 291-315, Vol. 38	

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	45.	CAMPBELL et al., "Cell-Based Gene Transfer to the Pulmonary Vasculature: Endothelial Nitric Oxide Synthase Overespression Inhibits Monocrotaline-Induced Pulmonary Hypertension," American Journal of Respiratory Cell and Mol. Biol., (1999), 567-575, Vol. 21	
	46.	COLTER et al., "Identification of a Subpopulation of Rapidly Self-Renewing and Multipotential Adult Stem Cells in Colonies of Human Marrow Stromal Cells," PNAS, (2001), p. 7841-7845, Vol. 98	
	47.	CONGET et al., "Adenoviral-mediated Gene Transfer into Ex Vivo Expanded Human Bone Marrow Mesenchymal Progenitor Cells," Experimental Hematology, (2000), p. 382-390, Vol. 28	
	48.	CONGET et al., "Phenotypical and Functional Properties of Human Bone Marrow Mesenchymal Progenitor Cells," Journal of Cellular Physiology, (1999), p. 67-73, Vol. 181	
	49.	DING et al., "Bone Marrow Stromal Cells as a Vehicle for Gene Transfer," Gene Therapy, , (1999), p. 1611-1616, Vol. 6	
2 13 1401 1 140	50.	ELICEIRI et al., "The Role of αV Integrins During Angiogenesis: Insights Into Potential Mechanisms of Action and Clinical Development," The Journal of Clinical Investigation, (1999), p. 1227-1230, Vol. 103, No. 9	
	51.	FUKAI et al., "Modulation of Apoptotic Cell Death by Extracellular Matrix Proteins and a Fibronectin-Derived Antiadhesive Peptide," Experimental Cell Research, (1998), p. 92-99, Vol. 242	
	52.	GAILIT et al., "Human Fibroblasts Bind Directly to Fibrinogen at RGD Sites Through Integrin αVβ3," Experimental Cell Research, (1997), p. 118-126, Vol. 232	
	53.	GIAID et al., "Expression of Endothelin-1 in the Lungs of Patients with Pulmonary Hypertension," The New England Journal of Medicine, (1993), p. 1732-1739, Vol. 328, No. 24	
	54.	GIANCOTTI, "Integrin Signaling: Specificity and Control of Cell Survival and Cell Cycle Progression," Current Opinion in Cell Biology, (1997), p. 691-700, Vol. 9	
	55.	GOMEZ-NAVARRO et al., "Genetically Modified CD34* Cells as Cellular Vehicles for Gene Delivery into Areas of Angiogenesis in a Rhesus Model," Gene Therapy, (2000), p. 43-52, Vol. 7	T

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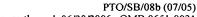
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	56.	GRONTHOS et al., "Integrin-Mediated Interactions Between Human Bone Marrow Stromal Precursor Cells and the Extracellular Matrix," Bone, (2001), p. 174-181, Vol. 28, No. 2	
	57.	JIANG. et al., "Pluripotency of Mesenchymal Stem Cells Derived from Adult Marrow," Nature, (2002), p. 41-49, Vol. 418	
	58.	KRAUSE et al., "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell," Cell, (2001), p. 369-377, Vol. 105	
	59.	KRAUSE, "Plasticity of Marrow-Derived Stem Cells," Gene Therapy, (2002), p. 754-758, Vol. 9	
	60.	KAMIYA et al., "Intracellular trafficking and Transgene Expression of Viral and Non-Viral Gene Vectors," Advanced Drug Delivery Reviews, (2001), p. 153-164, Vol. 52	
	61.	KOTTON et al., "Bone Marrow-Derived Cells as Progenitors of Lung Alveolar Epithelium," Development, (2001), p. 5181-5188, Vol. 128	
	62.	MINGUEL et al., "Mesenchymal Stem Cells," Exp. Biol. Med., (2001), p. 507-520, Vol. 226	
	63.	PASQUALINI et al., "A Study of the Structure, Function and Distribution of β5 Integrins Using Novel Anti-β5 Monoclonal Antibodies," Journal of Cell Science, (1993), 101-111, Vol. 105	
	64.	PEREIRA et al., "Cultured Adherent Cells from Marrow Can Serve As Long-Lasting Precursor Cells for Bone, Cartilage, and Lung in Irradiated Mice," Proc. National Academy Science USA, (1995), p. 4857-4861, Vol. 92	
	65.	PLATH et al., "A Novel Function for the Tumor Suppressor p16 <sup>INK4a</sup> . Induction of Anoikis via Upregulation of the α5β1 Fibronectin Receptor," The Journal of Cell Biology, (2000), p. 1467-1477, Vol. 150, No. 6	

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	66.	POWELL et al., "Gel Microdroplets and Flow Cytometry: Rapid Determination of Antibody Secretion by Individual Cells Within a Cell Population," Biotechnology, (1990), p. 333-337, Vol. 8	
	67.	REINECKE et al., "Taking the Death Toll After Cardiomyocyte Grafting: A Reminder of the Importance of Quantitative Biology," Journal Mol Cell Cardiol, (2002), p. 251-253, Vol. 34	
	68.	REINECKE et al., "Survival, Integration, & Differentiation of Cardiomyocyte Grafts, A Study in Normal and Injured Rat Hearts," Circulation, (1999), p. 193-202, Vol. 100	
	69.	RUBANYI, "The Future of Human Gene Therapy," Molecular Aspects of Medicine, (2001), p. 113-142, Vol. 22	
	70.	SCOTT et al., "Fibronectin Suppresses Apoptosis in Normal Human Melanocytes Through an Integrin-Dependent Mechanism," The Journal of Investigative Dermatology, (1997), p. 147-153, Vol. 108	
	71.	STUPACK et al., "Apoptosis of Adherent Cells by Recruitment of Caspase-8 to Unligated Integrins," The Journal of Cell Biology, (2001), p. 459-470, Vol. 155, No. 3	
	72.	THEISE et al., "Toward a New Paradigm of Cell Plasticity," Leukemia, (2002), p. 542-548, Vol. 16	
	73.	THIERRY et al., "Patterns of Engraftment in Different Strains of Immunodificient Mice Reconstituted with Human Peripheral Blood Lymphocytes," Transplantation, (2001), p. 133-140, Vol. 72, No. 1	
	74.	THURMOND et al., "A Deadly Game of Musical Chairs: Survival of Cells Transplanted for Myocardial Repair," Journal Mol Cell Cardiology, (2001), p. 883-885, Vol. 33	
	75.	TURCANU et al., "Cell Identification and Isolation on the Basis of Cytokine Secretion: A Novel Tool for Investigating Immune Responses," Nature Medicine, (2001), p. 373-376, Vol. 7, No. 3	

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SAPEN TOT I	orm 1449B/PTO			Complete if Known	
			~~~~	Application Number	10/540,743
INFO	RMATION	DISCLO	SURE	Filing Date	June 24, 2005
STAT	STATEMENT BY APPLICANT			First Named Inventor	Duncan J. STEWART
	Alaa aa mamu ahaa	do		Art Unit	Not Yet Assigned
(Use as many sheets as necessary)				Examiner Name	Not Yet Assigned
Sheet	8		9	Attorney Docket Number	3998-051955

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	76.	WANG et al., "Signaling Pathway for Apoptosis: A Racetrack for Life or Death," Journal of Cellular Biochemistry Supplements, (1999), p. 95-102, Vol. 32	
	77.	WEAVER et al., "Rapid Clonal Growth Measurements at the Single-Cell Level: Gel Microdroplets and Flow Cytometry," Bio/Technology, (1991), p. 873-877, Vol. 9	
	78.	WEAVER et al., "Gel Microdrop Technology for Rapid Isolation of Rare and High Producer Cells," Nature Medicine, (1997), p. 583-585, Vol. 3, No. 5,	
	79.	YOUNG et al., "Nonviral Gene Transfer Strategies for the Vasculature," Microcirculation, , (2002), p. 35-50, Vol. 9	
	80.	ZHANG, "Development and Application of Adenoviral Vectors for Gene Therapy of Cancer," Cancer Gene Therapy, (1999), p. 113-138, Vol. 6, No. 2	
	81.	ZHANG et al., "Cardiomyocyte Grafting for Cardiac Repair: Graft Cell Death and Anti-death Strategies," Journal of Molecular Cell Cardiology, (2001), p. 907-921, Vol. 33	
	82.	ZHANG et al., "The α5β1 Integrin Supports Survival of Cells on Fibronectin and Up-Regulates Bcl-2 Expression," PNAS, (1995), p. 6161-6165, Vol. 92	
	83.	WU et al., "Preliminary Report on Microencapsulated Islet Transplantation in Experimental Diabetes Mellitus in China," International Journal of Pancreatology, (1988), p. 91-100, Vol. 3, (abstract)	
	84.	AEBISCHER et al., "Macroencapsulation of Dopamine-Secreting Cells by Coextrusion with an Organic Polymer Solution," Biomaterials, (1991), p. 50-56, Vol. 12	
	85.	RUOSLAHTI et al., "New Perspectives in Cell Adhesion: RGD and Integrins," Science, (1987), p. 491-497, Vol. 238,	

Examiner	Date	•
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Complete if Known Application Number 10/540,743 INFORMATION DISCLOSURE Filing Date June 24, 2005 STATEMENT BY APPLICANT First Named Inventor Duncan J. STEWART Art Unit Not Yet Assigned (Use as many sheets as necessary) Examiner Name Not Yet Assigned Sheet 9 9 Attorney Docket Number 3998-051955

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	86.	COHEN et al., "Ionically Cross-Linkable Polyphosphazene: A Novel Polymer for Microencapsulation," Journal of American Chemistry Society, (1990), p. 7832-7833, Vol. 112	
	87.	WANG et al., "Sustained Reduction of Serum Cholesterol Levels Following Allo-Transplantation of Parenchymal Hepatocytes in Watanabe Rabbits," Transplantation Proceedings, (1991), p. 894-895, Vol. 23, No. 1	
	88.	GIAID et al., "Reduced Expression of Endothelial Nitric Oxide Synthase in the Lungs of Patients with Pulmonary Hypertension," The New England Journal of Medicine, (1995), p. 214-221, Vol. 333, No. 4	
	89.	GELBAND et al., "Current Perspectives on the Use of Gene Therapy for Hypertension," Circulation Research, The Journal of The American Heart Association, (2000), p. 1118-1122, Vol. 87	

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